

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Ksander, G.M., et al. Art Unit: 1626  
Examiner: Janet L. Coppins  
APPLICATION NO: 10/556,988  
FILED: February 3, 2006  
FOR: N-ACYL NITROGEN HETEROCYCLES AS LIGANDS OF  
PEROXISOME PROLIFERATOR-ACTIVATED RECEPTORS

**MS: General**  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**PETITION REGARDING PATENT TERM ADJUSTMENT UNDER C.F.R. §1.705(d)**

Sir:

In accordance with 37 C.F.R. § 1.705(d), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 646 days. This application is being filed within 2 months after issuance of the patent, as required by 37 C.F.R. § 1.705(d).

**I. Fee**

As required by 37 C.F.R. § 1.705(b)(1), this application is accompanied by a request to charge Deposit Account No. **50-4409** for \$ 200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account **50-4409**.

**II. Statement of the Facts Involved**

**A. Correct Patent Term Adjustment**

The Issue Notification, which was mailed on January 6, 2010, indicated a Patent Term Adjustment of 327 days.

Patentee has calculated an initial patent term adjustment of 646 days based on the following facts:

### Case Law

In *Wyeth v. Kappos*, 2010 U.S. App. Lexis 300, the Federal Circuit affirmed the interpretation of 35 U.S.C. § 154(b)(2) by the District Court of the District of Columbia in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 2008. The Federal Circuit affirmed the determination that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2)(B) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(2)(A) period and a 35 U.S.C. § 154(b)(2)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(2)(A) period that falls outside of the 35 U.S.C. § 154(b)(2)(B) period in addition to the 35 U.S.C. § 154(b)(2)(B) period itself.

### Relevant Dates

The above identified application has a 35 U.S.C. §371 filing date of February 3, 2008.

The first Office Action, which was a Restriction Requirement, was mailed on March 17, 2008, resulting in a PTO delay of 349 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed April 17, 2008, within the 3 months provided by 35 U.S.C. §154(b).

An Office Action was mailed July 8, 2008, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed October 8, 2008, within the 3 months provided by 35 U.S.C. §154(b).

A second Office Action was mailed on February 4, 2009, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed June 3, 2009, resulting in a 30 day delay beyond the 3 months provided by 35 U.S.C. §154(b).

A Notice of Allowance was mailed June 24, 2009, within the 4 months provided by 35 U.S.C. §154(b).

The issue fee was paid on September 23, 2009 within the 3 months provided by 35 U.S.C. §154(b).

The patent issued on January 26, 2010, resulting in a 3 day delay beyond the 4 months provided by 35 U.S.C. §154(b).

Accordingly, the PTO adjustment based on delay under 35 U.S.C. § 154(b)(1)(A) is 349 days plus 3 days, or 352 days. The reduction in term adjustment due to applicant delay under 35 U.S.C. § 154(b)(2)(C) is 30 days, resulting in a patent term adjustment of 322 days.

The 35 U.S.C. § 154(b)(1)(B) period for the instant application began on February 3, 2009 (three years after the requirements of 35 U.S.C. § 371 were met on February 3, 2006) and ended on January 26, 2010, the date of issuance. The 35 U.S.C. § 154(b)(1)(B) period running from February 3, 2009 until issuance of the patent (January 26, 2010) is 357 days. The reduction in term adjustment due to applicant delay is 30 days, resulting in an initial patent term adjustment of 327 days under 35 U.S.C. § 154(b)(1)(B).

Three days of PTO delay under 35 U.S.C. § 154(b)(1)(A) overlapped with PTO delay that occurred under 35 U.S.C. § 154(b)(1)(B) and should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Kappos*.

Accordingly, the sum of the 35 U.S.C. § 154(b)(1)(B) delay (327 days) and non-overlapping 35 U.S.C. § 154(b)(1)(A) delay (322 days minus 3 days, or 319 days) is 646 days.

The PTA printed on the Issue Notification is only 327 days, which the USPTO is presumed to have calculated using the method considered proper before the holding of *Wyeth v. Kappos*. Applicants therefore respectfully request reconsideration of the PTA calculation.

#### **B. Terminal Disclaimer**

The above-identified patent is not subject to a Terminal Disclaimer.

**C. Reasonable Efforts**

Any applicant delays under 37 C.F.R. § 1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Respectfully submitted,

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Date: March 11, 2010